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SYMED LABS LIMITED and HETERO USA, INC., Plaintiffs, v. GLENMARK PHARMACEUTICALS INC., USA, Defendant.	UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY CIVIL ACTION NO. **COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs, Symed Labs Limited ("Symed") and Hetero USA, Inc. ("Hetero"; collectively with Symed, "Plaintiffs"), by way of Complaint against Defendant, Glenmark Pharmaceuticals Inc., USA ("Glenmark" or "Defendant"), allege as follows:

THE PARTIES

1. Symed is a corporation organized and existing under the laws of India with its corporate headquarters at Bhavya Sree Arcade, 8-3-166/7/1, Erragadda Main Rd, Vikaspuri, Erragadda, Hyderabad, Telangana 500018 India.

2. Hetero is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

3. Glenmark is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 750 Corporate Drive, Mahwah, New Jersey. Glenmark is registered to do business in the State of New Jersey and maintains a registered agent for service of process in New Jersey.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has jurisdiction over Defendant because, under information and belief, Defendant has a principal place of business in this judicial district, and is in the business of manufacturing, marketing, importing and/or selling pharmaceutical drug products throughout the United States, the State of New Jersey and in this judicial district. Upon information and belief, Defendant purposefully conducts and continues to conduct business, directly or indirectly, in this judicial district, and this judicial district is a target for Defendant's infringing products. Upon information and belief, Defendant receives substantial income from the sale of its products within New Jersey and this judicial district. Upon information and belief, Defendant maintains continuous and systematic contacts with New Jersey and its citizens directly or through its related companies, affiliates and/or authorized agents.

6. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

THE PATENTS IN SUIT

7. Plaintiffs are the owners by assignment of U.S. Patent No. 7,714,128 (the "'128 Patent") entitled "Crystalline Form of Linezolid," duly issued by the United States Patent and Trademark Office on or about May 11, 2010. The '128 Patent is annexed hereto as Exhibit A.

8. Plaintiffs are the owners by assignment of U.S. Patent No. 7,732,597 (the "'597 Patent") entitled "Crystalline Form of Linezolid," duly issued by the United States Patent and Trademark Office on or about June 8, 2010. The '597 Patent is annexed hereto as Exhibit B.

9. The '128 Patent and the '597 Patent are collectively referred to herein as the "Asserted Patents."

10. The Asserted Patents claim a novel form of linezolid ("Form III Linezolid") and processes for the preparation of Form III Linezolid.

ACTS GIVING RISE TO THIS ACTION

11. Upon information and belief, Defendant has already used, made and/or offered for sale, and is preparing to sell Plaintiffs' patented Form III Linezolid and perform the processes for the preparation of Form III Linezolid covered by the Asserted Patents.

12. Upon information and belief, there are three known forms of linezolid: Form I in the prior art which is unstable and not suited for medical use; Form II as to which a third party maintains a U.S. patent; and Form III which is patented by Plaintiffs.

13. Upon information and belief, Defendant submitted Abbreviated New Drug Application ("ANDA") No. 078987 to the United States Food and Drug Administration (the "FDA") seeking approval to manufacture, use and/or sell linezolid 600 mg tablets (the "Infringing Product") and received tentative approval for same on or about April 27, 2009, subject to a marketing exclusivity period of a third party drug manufacturer. Upon information and belief, Defendant's ANDA application stated that it did not infringe the patent on Form II.

14. On or about January 29, 2015, Symed caused a letter to be sent to Defendant advising Defendant, among other things, of Symed's ownership of the Asserted Patents "in

relation to the Linezolid API, as well as methods of manufacture, and intermediates that can be used in processes for manufacture of Linezolid."

15. Despite repeated requests, Defendant has refused to provide Plaintiffs with samples of the linezolid product it is making, using, and offering for sale in the United States; has not provided characterization data (such as x-ray powder diffraction data or infrared spectrum data) for its product, and has not identified the actual processes being used by Defendant and/or its manufacturer to make linezolid for the United States market.

16. Upon information and belief, there are no processes known or used to make Form III Linezolid other than those identified in the '597 Patent (or one of two other patents owned by Plaintiffs).

17. In addition, Defendant's U.S. Patent No. 7,649,096 entitled "Process for the preparation of a crystalline form of (S)-N [[3-(3-fluoro-4(4-morpholinyl) phenyl]-2-oxo-5-oxazolidinyl] methyl] acetamide," issued by the United States Patent and Trademark Office without consideration of Plaintiffs' patents, further demonstrates Defendant's intent to infringe the Asserted Patents.

18. Upon due investigation, and upon information and belief, Defendant's linezolid product and processes used to make same infringe one or more claims of the Asserted Patents.

FIRST COUNT
(Patent Infringement – the '128 Patent)

19. Plaintiffs repeat and reallege the allegations contained in the preceding paragraphs as if stated fully herein.

20. Upon information and belief, Defendant is making, using, offering for sale and intends to sell the Infringing Product in the United States.

21. Defendant's manufacture, use, offer for sale, sale, and/or importation of the Infringing Product in the United States constitutes infringement of one or more claims of the '128 Patent in violation of 35 U.S.C. § 271(a).

22. Absent injunctive and other relief, Plaintiffs will suffer substantial and irreparable injury for which Plaintiffs have no adequate remedy at law.

SECOND COUNT
(Patent Infringement – the '597 Patent)

23. Plaintiffs repeat and reallege the allegations contained in the preceding paragraphs as if stated fully herein.

24. Upon information and belief, Defendant is making, using, offering for sale and intends to sell the Infringing Product in the United States.

25. Defendant's manufacture, use, offer for sale, sale, and/or importation of the Infringing Product in the United States necessarily constitutes infringement of one or more claims of the '597 Patent in violation of 35 U.S.C. § 271(a).

26. Absent injunctive and other relief, Plaintiffs will suffer substantial and irreparable injury for which Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs, Symed Labs Limited and Hetero USA, Inc., demand judgment against Defendant, Glenmark Pharmaceuticals Inc., USA, as follows:

(a) Judgment that manufacturing, using, offering for sale, selling, and importing the Infringing Product infringes one or more claims of the Asserted Patents;

(b) Judgment permanently enjoining Glenmark Pharmaceuticals Inc., USA from manufacturing, using, offering for sale, selling, and importing the Infringing Product until after the expiration of the Asserted Patents;

(c) Judgment awarding damages to Plaintiffs for Defendant's unlawful conduct;

(d) Attorneys' fees in this action pursuant to 35 U.S.C. § 285;

(e) Costs and expenses in this action; and

(f) Such other and further relief as the Court deems just and proper under the circumstances.

JURY DEMAND

Plaintiffs demand a trial by jury on all issues so triable.

DATED: November 25, 2015

Respectfully submitted,

COLE SCHOTZ P.C.

By: */s/ Michael S. Weinstein*

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